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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/435,504	11/06/1999	DENNIS SUNGA FERNANDEZ	FERN-P006	5319

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EXAMINER	
RINES, ROBERT D	
ART UNIT	PAPER NUMBER
3623	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/435,504	FERNANDEZ, DENNIS SUNGA	
	Examiner	Art Unit	
	R. David Rines	3623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 October 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 21-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 21-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Notice to Applicant

[1] This communication is in response to the amendment filed 18 October 2010. The Information Disclosure Statements (IDS) filed 23 December 2010 and 18 October 2010 have been entered and considered. Claims 13-20 have been cancelled. Claims 1, 21, 26, 27, and 28 have been amended. Claims 1-12 and 21-28 are pending.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

[2] Previous rejection of claims 1-12 and 21-28 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement have been overcome by cancellation of the subject recitation/limitation (e.g. “protein folding structure") and are hereby withdrawn.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

[3] Previous rejection of claims 1-12 and 21-27 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention have been overcome by the amendments to the subject claims and are hereby withdrawn.

Claim 1 as presented by amendment recites "…wherein such transaction comprises detecting genetic discrimination or fraud by detecting identical genetic terms from genetic samples of a plurality of transacting discrimination identical genetic terms from genetic samples of a plurality of transacting users, such identical genetic terms from different transacting users enabling detection of possible fraudulent sequence clone or twin matching wherein the transacting users that are detected to have identical genetic terms are not actually true sequence clones or matching twins, or possible discrimination of true sequence clones or matching twins when the transacting users are classified in the same genetic group or class do not obtain substantially fair or equitable transaction terms…"

It is unclear what is being "detected" as fraudulent and/or discrimination. Particularly, it is not clear whether submitting an identical sequence constitutes fraud or discrimination of whether having a twin or clone is considered fraudulent or discriminatory. While Examiner is aware that

a personal genetic make-up can serve to identify an individual and or categorize an individual as belonging to a risk group, it is not clear that individuals having sequences in common can be automatically classified as twins or clones. For example, individuals having an identical sequence with respect to particular genes are not necessarily twins or clones. As mentioned above, it is further unclear how being a twin is a "fraudulent" condition. The Specification reiterates the claim language and provides no further explanation of how these functions are performed and what is considered discrimination and/or fraud. For purposes of applying art, Examiner assumes that a sequence comparison is performed in order to classify individuals into categories deemed relevant to a transaction. However, Examiner's interpretation is not clear from the claim as presented and appropriate clarification/correction is required.

Claims 2-12 and 21-26 inherit the deficiencies of independent claim 1 through dependency and when analyzed in the same manner described above with respect to claim 1, are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which the applicant regards as the invention.

Claim 27, when analyzed in the manner described above with respect to claim 1 is also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

[4] Claims 1, 10-12, 21, 27, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holden (United States Patent #6,640,211) in view of Messier et al. (United States Patent #6,228,586).

The unamended limitations in claims 1, 10-12, 21, 27, and 28 are rejected/addressed by the teachings of Holden as presented in the previous Office Action mailed 8 December 2009 and as indicated in the Decision of the Board of Patent Appeals and Interferences mailed 6 March 2006.

Claim 1 further recites functions performed by the recited processor. The elements and features added by amendment are disclosed by Holden.

Specifically, Holden discloses "wherein the processor processes the bioinformatic value automatically using one or more data structure comprising one or more user identifier field and genetic sequence subset, mask, screen or filter field, such that a user reference sequence is processable securely by the processor in an authorized transaction using the genetic sequence subset, mask, screen or filter field to qualify or evaluate one or more participating user (Holden; col. 1, lines 35-42, col. 2, lines 48-65, col. 4, lines 1-15 *see authorized access to digital genetic information and patient establishes settings for uses of the genetic information, i.e., information is "processable securely…in an authorized transaction").

Holden further discloses "such one or more data structure comprising one or more application-specific transaction control and payload fields, and processed digitally in an representative electronic signal form which is encoded, compressed, transmitted, stored, received and decoded, according to one or more secure signal or data modulation scheme, such one or more data structure further referring to or reference uniquely one or more personally identifiable alphanumeric or text string, electronic signal, or representative digital information that classifies or processes the user bioinformatic value according to volunteered permitted, or user-authorized mask, screen, filter or logical criteria for defining, recognizing, identifying, or generating one or more subset or sequence portion of a more complete, reference, or generalized genetic sequence associated with the user or other reference entity"(Holden: col. 2, lines 25-38, col. 3, lines 45-67 and col. 4, lines 1-45 *see voluntary submission and access settings authorizing test for marker sets and genotypes, i.e., a "filter or mask" allowing access to "portion or location of genetic information").

Holden additionally discloses " such one or more data structure further comprising a reference sequence, a mask subset, indexing flags, and a classification object, such that such one or more data structure serves to mask functionally the bioinformatic value according to user authorization or permit of network transaction activity, whereby automatically selective bioinformatic segment revelation limits disclosure deliberately by the user only to personal gene sequence location associated with the transaction evaluation and related personal risk" (Holden: col. 2, lines 25-38 and lines 49-65, col. 3, lines 45-67 and col. 4, lines 1-45 *see authorized test for marker sets and genotypes, i.e., a "filter or mask" allowing access to "portion or location of genetic information" *see further "patient has control to access for third parties and can dictate purposes for the access").

Claim 1 has been amended to further specify "…wherein such transaction comprises detecting genetic discrimination or fraud by detecting identical genetic terms from genetic samples of a plurality of transacting discrimination identical genetic terms from genetic samples of a plurality of transacting users, such identical genetic terms from different transacting users enabling detection of possible fraudulent sequence clone or twin matching wherein the transacting users that are detected to have identical genetic terms are not actually true sequence clones or matching twins, or possible discrimination of true sequence clones or matching twins when the transacting users are classified in the same genetic group or class do not obtain substantially fair or equitable transaction terms…"

As per these elements, Holden discloses a genetic profile database that allows individuals to access the profile for authorized purposes. Specifically, Holden discloses digital certificates and password protection to access user submitted DNA sequence information (Holden; col. 3, lines 53-65 and col. 4, lines 1-26). Examiner considers this teachings to constitute a securing the data against a i.e., a restricted transaction (*see rejection(s) under 35 U.S.C. 112, second paragraph above).

Holden further discloses that is well known to identify or categorize an individual as at risk for a particular disease based on personal genetic make-up, i.e., identifying an individual as belonging to a risk group" (Holden; col. 3, lines 45-67 and col. 4, lines 1-45 *see rejection under 35 U.S.C. 112, second paragraph above). Examiner considers the sequence comparison of Holden et al. to constitute a transaction, at least insofar as claimed.

With respect to the comparison of sample sequences, Holden discloses a voluntarily submission and authorized access to a patient's DNA sequence and genetic profile. Holden further discloses comparison of patient DNA sequence and specific SNP's are correlated to disease phenotypes (Holden; col. 3, lines 52-67 and col. 4, lines 34-60). Holden fails to provide and example of a genotypic and proteomic analysis to produce a correlation.

However, as evidenced by Messier et al. it is well known in the art that particular genotypic variances are related to peptide sequence differences/protein peptide sequence and conformational changes. Further, it is well known to perform disease predisposition analyses which include analysis of nucleotide sequence markers and a conformational/sequence change in the associated protein (Messier et al.; col. 8, lines 16-52 and col. 10, lines 5-35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the SNP/DNA sequence comparison methods disclosed by Holden with the well known practice of translating DNA sequence into peptide sequence to determine a change in the protein as disclosed by analogous reference Messier et al. The motivation to make the noted modification would have been to identify significant sequence changes that can be utilized in the development of treatments for human conditions or diseases.

Claims 27 and 28 as presented by amendment substantially repeat the limitations of amended claim 1. Accordingly, claims 27-28 are rejected for the reasons, conclusion of obviousness, and statements of motivation as discussed above with respect to claim 1.

Claims 2-4, 6-9, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Holden in view of Messier et al. as applied to claim 1 above, and further in view of "Genetic Tests: Evolving Policy Question" by Asch, as presented in the previous Office Action mailed 8 December 2009 and as indicated in the Decision of the Board of Patent Appeals and Interferences mailed 6 March 2006.

The unamended limitations in claims 2-4, 6-9, and 22 are rejected/addressed by the teachings of Holden in view of "Genetic Tests: Evolving Policy Question" by Asch as presented in the previous Office Action mailed 8 December 2009 and as indicated in the Decision of the Board of Patent Appeals and Interferences mailed 6 March 2006.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Holden (United States Patent #6,640,211) in view of Messier et al. (United States Patent #6,228,586) as applied to claim 1 above, and further in view of O'Flaherty (United States Patent #6,275,824), as presented in the previous Office Action mailed 8 December 2009 and as indicated in the Decision of the Board of Patent Appeals and Interferences mailed 6 March 2006.

The unamended limitations in claims 2-4, 6-9, and 22 are rejected/addressed by the teachings of Holden in view of O'Flaherty as presented in the previous Office Action mailed 8 December 2009 and as indicated in the Decision of the Board of Patent Appeals and Interferences mailed 6 March 2006.

Response to Remarks

Applicant's remarks filed 18 October 2010 have been fully considered but they are not persuasive. The remarks will be addressed as presented in the noted response.

Applicant provides a single remark which notes multiple claim limitations preceded by a generic statement indicating that the applied references fail to provide teachings of any of the following. In this instance, in which no other commentary is provided other than to make a general statement of disagreement concerning the applied teachings as they relate to multiple claim limitations, Examiner cannot determine which elements of the claim Applicant views as not taught by the applied art. In response to the noted remarks, Examiner relies on the applied teachings, conclusions of obviousness, and statements of motivation presented in the instant Office Action, in the previous Office Actions mailed 29 September 2010, 7 June 2010, and 8 December 2009 as well as the Decision of the BPAI mailed 5 March 2008.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to R. David Rines whose telephone number is (571)272-5585. The examiner can normally be reached on 8:30am - 5:00pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Beth Boswell can be reached on 571-272-6737. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. David Rines/
Primary Examiner, Art Unit 3623